

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: Decision Memorandum

Extension for NCER Assistance Agreement RD83329301

Title: Southern Center on Environmentally Driven Disparities in Birth Outcomes

Institution: Duke University

Principal Investigator: Marie Lynn Miranda (University of Michigan)

FROM:

Sylvana Li, Division Director

National Center for Environmental Research (8723P)

TO:

Christopher Zarba, Director (Acting)

National Center for Environmental Research (8701P)

I. Requirements

The purpose of this memorandum is to request approval for a deviation from 40 CFR Part 40.125-1(b). This deviation will allow grant RD83329301 with Duke University to be extended for two years at no cost. Both the project and budget periods for this assistance agreement are currently 05/01/2007 to 04/30/2012. The extension being requested would result in a seven-year duration with new project and budget periods of 05/01/2007 to 04/30/2014. This is expected to be the only extension of this assistance agreement's duration.

II. Background

This grant was awarded to Duke University as a result of a 2005 Science to Achieve Results (STAR) *Request for Applications* for Centers for Children's Environmental Health and Disease Prevention Research (CEHCs). Specific goals of the Duke University Southern Center on Environmentally Driven Disparities in Birth Outcomes (SCEDDBO) include: 1) to develop and operate an interdisciplinary children's health research center with a focus on understanding how biological, physiological, environmental, and social aspects of vulnerability contribute to health disparities; 2) to enhance research in children's health at Duke by promoting research interactions among programs in biomedicine, environmental health, and the social sciences and establishing an infrastructure to support and extend interdisciplinary research; 3) to develop new methodologies for incorporating innovative statistical analysis into children's environmental health research and policy practice, with a particular emphasis on genetic and spatial analysis; 4)

to serve as a technical and educational resource to the local community, region, the nation, and to international agencies in the area of children's health and health disparities; and 5) to translate the results of the Center into direct interventions in clinical care and practice.

The Southern Center on Environmentally-Driven Disparities in Birth Outcomes consists of 3 projects and 3 Cores. Research Project A is entitled "Mapping Disparities in Birth Outcomes," Research Project B is "Healthy Pregnancy, Healthy Baby: Studying Racial Disparities in Birth Outcomes" and Research Project C is "Perinatal Environmental Exposure Disparity and Neonatal Respiratory Health." The Center is organized around an Administrative Core, there is a Geographic Information Systems and Statistical Analysis Core and a Community Outreach and Translation Core. Synergies and complementarities exist across all research projects and cores, while overlap exists between each pair of research projects, as well as among all three research projects.

III. Purpose

The Duke University Children's Center is requesting a two-year no-cost extension from April, 2012 to April 2014. The extension is necessary in Project A to obtain the 2010 birth record data, to analyze whether changes in the built environment are reflected in changing pregnancy outcomes, complete the geocoding of data and complete data and statistical analysis. For Project B, the investigators need the additional time to complete data analysis and prepare manuscripts, connect the data with the psychosocial, genetic and physical health of mothers and infants in the clinical project, finish developing and validating statistical methods for genetic, clinical and environmental data interaction analysis, and characterize the complex interactions between three categories of factors that might influence pregnancy outcomes: host, social and environmental contributors, compile results and disseminate information to the community. For Project C, additional time is needed for data analysis to determine the window of vulnerability for maternal inhalational exposure to PM and diesel exhaust that may worsen the effects of postnatal ozone on airway hyperreactivity (asthma model) and on lung alveolar structure and to understand the nature of time-specific responses to environmentally relevant concentrations of diesel exhaust, to complete analyses on materials collected to assess effects of altered immune response pathways (host susceptibility) on postnatal lung structure and function. All of these analyses for all 3 projects are part of the original specific aims of the proposal.

The remaining funds are sufficient to complete the work within the 2-year extension period. NCER has determined that this extension is justified and will enable the recipient to complete the work as originally planned. The scope of work of the project has not changed and the project investigators have complied with the terms and conditions of the award agreement. This study has been progressing satisfactorily and will produce results that are likely to be useful to protect children's and maternal health, prevent adverse birth outcomes, understand social factors, gene and environment interactions important in children's health.

IV. Recommendations

- 1. Approval of a deviation from 40 CFR Part 40.125-1(b) that would allow the project and budget periods for grant RD83329301 to be extended by two years.
- 2. A new project period for grant RD83329201 of 05/01/2007 to 04/30/2014
- 3. A new budget period for grant RD83329201 of 05/01/2007 to 04/30/2014

Concur: Yes No	
Christopher Zarba, Director (Acting) National Center for Environmental Research	Date
Director, Office of Resources Management and Administration	Date
Senior Resource Official	Date